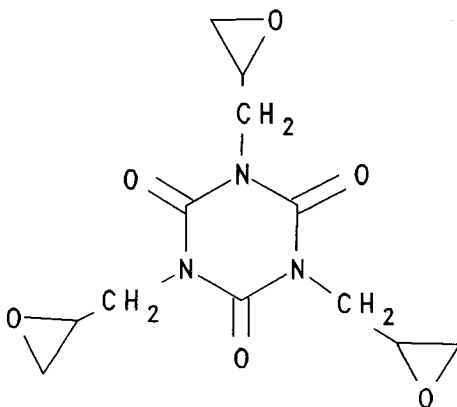


# TEROXIRONE

NSC - 296934



**Chemical Name:** 1,3,5-Tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione

**Other Names:** Henkel's Compound; Triazinetrione triepoxide;  $\alpha$ -Triglycodyl isocyanurate;  $\alpha$ -TGI, Teroxirone (USAN)

**CAS Registry Number:** 2451-62-9

**Molecular Formula:** C<sub>12</sub>H<sub>15</sub>N<sub>3</sub>O<sub>6</sub>

**M.W.:** 297.3

**How Supplied:** For injection, 100 mg, vial: supplied as a white lyophilized powder with 200 mg of mannitol, USP, in a 20 mL flint vial.

**Solution Preparation:** 100 mg/vial: When constituted with 10 mL of Sterile Water for Injection, USP, each milliliter contains 10 mg of teroxirone and 20 mg of mannitol, USP, at pH 6.0 to 8.0.

**Storage:** Store the intact vials under refrigeration.

**Stability:** Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for at least 3 years at refrigeration temperature (2-8 °C). Intact vials are unstable when stored at elevated temperature (50 °C).

Solutions of teroxirone are most stable at around pH 6. A study of teroxirone 5 mg/mL in various buffer systems over a pH range of 3 to 9.7 at 25 °C yielded the following data at 4 and 24 hours:

**Percent Of Teroxirone Remaining**

pH	4 Hrs.	24 Hrs.
3	89	49
5.5	97	76
6.4	97	79
7.5	91	57
9.7	92	49

The constituted solution of teroxirone exhibits approximately 2 to 5% decomposition in 4 hours at room temperature (22-25 °C).

Further dilution to a concentration of 0.1 mg/mL in 0.9% Sodium Chloride Injection, USP, results in a solution exhibiting about 2% decomposition in 2 hours and 8 to 10% in 4 hours at room temperature (22-25 °C) or under refrigeration (2-8 °C). Teroxirone is much less stable in 5% Dextrose Injection, USP, exhibiting approximately 12% decomposition in 2 hours and 17% in 4 hours.

At concentrations of 0.19, 1.0 and 2.4 mg/mL in 0.9% Sodium Chloride Injection, USP, at 37 °C, teroxirone decomposes 10% in 111, 126, and 162 minutes, respectively. After 4 hours at 37 °C, teroxirone losses of 21, 16, and 15% were observed at the three concentrations, respectively.

**Route of Administration:** Intravenous